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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Kenji Sunagawa

KUP-5

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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

07/08/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/523,539	Applicant(s) SUNAGAWA ET AL.	
	Examiner MICHAEL KAHRELIN	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 7-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 7 and 12 recite that the impulse response is calculated from an inverse Fourier transform of a transfer function which is based on a Fourier transform of normal-activity biosignals from the normal biological activities. However, Applicant asserted in the "Remarks" of 4/27/2009 that the claims are not intended to include an element to calculate any of the impulse response, the inverse Fourier transform, or the Fourier transform. The Examiner's position is that the "wherein" clause of claims 7 and 12 is vague because it would indicate to an artisan of ordinary skill that the system calculates an impulse response, inverse Fourier transform, and Fourier transform. It is unclear how this language can be both a limitation to the claimed system, while still not being a recited element of the claimed system, as method steps *per se* are not given patentable weight in a system claim. It is suggested to recite this subject matter in a way such that an artisan of ordinary skill would recognize that this is not a structural limitation on the system claims. Further, claim 10 recites that the "means" is "electrical stimulation" or "stimulation with the use of devices for drug administration." Since a "means" is a structure, it is unclear how "electrical stimulation"

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can be a tangible structure corresponding to the “means” language. It is suggested to recite something similar to “an electrical stimulation means.”

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shalev (US 2006/0089678, hereinafter “Shalev”) in view of Constant (US 4,006,351, hereinafter “Constant”).

6. In regards to claims 7 and 12, Shalev discloses the essential features of the claimed invention including a biological activity sensing means that senses biological activity and outputs a plurality of input biosignals (Fig. 2, element 20); a calculating means that receives the input biosignals, calculates a plurality of stimulation signals,

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and outputs the stimulation signals for stimulation of the organism (element 24); and an organism stimulating means that receives the stimulation signals and stimulates the organism based on the signals (element 26), depending on whether the input biosignals are caused by normal or abnormal biological activities (pars. 0062 and 0063). Although Shaley discloses that the calculating means utilizes a transfer function based on previous responses obtained from normal biologic activity (par. 0062 and Fig. 1B), Shaley does not explicitly disclose that the stimulation signal is calculated from a convolution integral between an impulse response previously obtained and the input signals. However, Constant teaches a calculating means for applying transfer functions wherein the output signal is calculated from a convolution integral between an impulse response previously obtained and the input signals (abstract) to provide the predictable results of a better measurement of time delay and frequency relationships in a noisy environment (col. 5, lines 37-48). Therefore, it would have been obvious to one having ordinary skill in that art at the time the invention was made to modify Shalev's invention by providing a calculating means for applying the transfer function wherein the output signal is calculated from a convolution integral between an impulse response previously obtained and the input signal to provide the predictable results of a better measurement of time delay and frequency relationships in a noisy environment. Due to Applicant's position that the claims do not require that the system calculate the impulse response using a Fourier transform and inverse Fourier transform, the Examiner is of the position that Shalev's modified system is capable of calculating stimulation signals using a

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impulse response calculated in the way recited in the "wherein" clause of claim 7, or an impulse response calculated in any other way.

7. In regards to claims 8 and 9, the sensing means is a pressure sensor and the activity is blood pressure (element 20).

8. In regards to claim 10, the stimulating means is an electrical stimulating means (par. 0063).

9. In regards to claim 11, Shaley's modified invention discloses the essential features of the claimed invention including a signal conditioner (106), an A/D converter (108), and an analyzer (110), but does not explicitly disclose that the signal conditioner includes an amplifier. However, it is notorious in the electrical stimulation and arts to provide signal sensing means with amplifiers to provide the predictable results of maximizing the signal of interest and minimizing noise. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Shaley's invention by providing the signal sensing means with an amplifier to provide the predictable results of maximizing the signal of interest and minimizing noise

Conclusion

10. Applicant's amendments to the claims and Applicant's corresponding disclaimer of calculating the impulse response, Fourier transform, and inverse Fourier transform (See "Remarks," filed 4/27/2009) necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Kahelin/
Examiner, Art Unit 3762

/Angela D Sykes/
Supervisory Patent Examiner, Art Unit 3762